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EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,769	SAUVAIGO, SYLVIE	
	Examiner	Art Unit	
	MICHELE K. JOIKE	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 4, 2009 has been entered.

Claims 22-50 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed September 4, 2008 that is not addressed in this action has been withdrawn.

Claim Objections

Claim 40 is objected to because of the following informalities: The claim needs a period at the end. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step (d), the support is incubated with various repair solutions. However, the solution optionally contains repair enzymes and other necessary components. In the specification, it states that the biological medium may contain repair enzymes. Again, it is optional. If the repair solution does not contain repair enzymes, how are the lesions being repaired?

"Biological medium" is an indefinite term. Medium is usually used to mean nutrient agar or broth deigned to grow cells. The reference to biological medium in the specification is "[t]he term "biological medium" or "cell extract" refers to a purified by unpurified biological preparation that may contain at least one enzyme activity related to DNA repair" (paragraph 24). It is unclear what a biological preparation is. In other words, what does the biological medium contain?

In claim 42, it is unclear how assessing whether DNA lesions are repaired in supercoiled plasmids diagnoses diseases. The method steps in claim 22 are used to determine whether DNA lesions have been repaired. This does not relate to diagnosing DNA repair-related diseases. If a DNA lesion is repaired, it does not follow that a DNA repair-related disease has just been diagnosed.

Applicant's arguments, see pages 2-6, filed May 4, 2009, with respect to the rejection(s) of claim(s) 22-25, 31, 33, 38, 41-44, 47 and 50 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Applicants argue that the US 2002/0022228 does not teach constructing supercoiled plasmid DNA for the quantitative assessment, that instead plasmid DNA is used to make oligonucleotides to assess DNA repair. This found persuasive, however, a new rejection is made below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 in view of Calsou et al.

US 2002/0022228 (see paragraphs 1, 32, 39, 40, 43, 55, 57, 58, 62, 79, 80, 88, 96, 104-110 and examples) teach a method for analyzing DNA repair by excision and resynthesis. The DNA containing lesions are placed on a support, including a glass slide or an array. The lesion can be chemically created or treated with UV irradiation. More than one agent can be used, for example, methylene in conjunction with visible light. The array is used to test multiple lesions, and the nature of an array is a solid support with divided zones for assessing different solutions. There is also control (wild type) DNA. When the sample has been immobilized on the support, it is washed, and treated with DNA repair enzymes. The DNA can be labeled with fluorescence-labeled nucleotide triphosphates and scanned to detect if modifications are still present, and

compared to the control. The DNA can be double-stranded. The buffer used can have a pH of 7.6. 100 pmol DNA molecules/ml are used. This reference also reads on the methods to establish a repair profile, diagnose a repair-related disease, to assess the influence of a physical or chemical treatment means on repair capacities and for screening substances capable of modulating a repair system (claims 41-44) since these methods all comprise the exact same steps. However, it does not teach the use of supercoiled plasmid DNA.

Calsou et al (J Biol Chem. 1996 Nov 1;271(44):27601-7, especially materials & methods) teach measuring nucleotide excision repair and DNA resynthesis, using supercoiled plasmids. The plasmids were mutated with either UV irradiation or cisplatin. The plasmids were purified by sucrose gradient centrifugation, and all of the plasmids were in supercoiled form. A control supercoiled plasmid with no lesions was also used. DNA repair activity was assayed and quantified.

The ordinary skilled artisan, desiring to perform a method for analyzing DNA repair by excision and resynthesis using supercoiled plasmids would have been motivated to combine the teachings of US 2002/0022228 teaching a method for analyzing DNA repair by excision and resynthesis with the teachings of Calsou et al teaching measuring nucleotide excision repair and DNA resynthesis, using supercoiled plasmids, because Calsou et al state that excision repair of linear plasmids was reduced by 80% as compared to supercoiled plasmids. It would have been obvious to one of ordinary skill in the art because Calsou et al teach that supercoiled plasmids allow for more efficient repair. Given the teachings of the prior art and the level of the ordinary

skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/00222288 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Douki et al.

US 2002/0022228 and Calsou et al teach all of the limitations as described above. However, they do not teach digesting the plasmids and analyzing them by HPLC coupled to mass spectrometry.

Douki et al (Nuc. Acid Res. 32(12): 3134-3142, 2003, specifically pp. 3134-44) teaches digesting DNA exposed to UV irradiation and analyzing the digested DNA by HPLC coupled with mass spectrometry. Nuclease P1 was used for the digestion.

The ordinary skilled artisan, desiring to digest DNA with P1 nuclease that has been exposed to UV irradiation and analyzing the digested DNA by HPLC coupled with mass spectrometry would have been motivated to combine the teachings of US 2002/0022228 teaching a method for analyzing DNA repair by excision and resynthesis with the teachings of Calsou et al teaching measuring nucleotide excision repair and DNA resynthesis, using supercoiled plasmids, with the teachings of Douki et al, teaching digesting DNA exposed to UV irradiation and analyzing the digested DNA by HPLC coupled with mass spectrometry, because Douki et al state that HPLC associated with tandem mass spectrometry represents an interesting alternative to achieve a more

specific quantification of UV-induced DNA products. It would have been obvious to one of ordinary skill in the art because Douki et al teach that HPLC-MS can be used to quantify nucleosides that have been released by phosphodiesterases or P1 nucleases. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of MPEP 2144.05.

US 2002/0022228 and Calsou et al teach all of the limitations as described above. However, they do not teach a plasmid concentration of 5 to 100 µg/ml.

MPEP 2144.05 teaches that optimizing concentrations is obvious.

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler,* 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

MPEP 2144.05

Therefore, since there is no evidence that using a concentration of 5 to 100 µg/ml of plasmid DNA is significant, it would be obvious to adjust the amount of plasmid concentration taught by US 2002/0022228 to 5 to 100 µg/ml. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Chiu et al.

US 2002/0022228 and Calsou et al teach all of the limitations as described above. However, they do not teach sensitizing a glass slide with an epoxy group. It does teach the support comprising different zones, as discussed above.

Chiu et al (Biochem. 374(3):625-32, 2003, specifically p. 625) teach using an epoxy group to treat a glass slide.

The ordinary skilled artisan, desiring to use an epoxy group to treat a glass slide would have been motivated to combine the teachings of US 2002/0022228 teaching a method for analyzing DNA repair by excision and resynthesis and Calsou et al teaching measuring nucleotide excision repair and DNA resynthesis, using supercoiled plasmids, with the teachings of Chiu et al, teaching using an epoxy group to treat a glass slide, because Chiu et al state that epoxysilane will increase the binding capacity and efficiency of hybridization of DNA on the glass surface. It would have been obvious to one of ordinary skill in the art to use an epoxy group because Chiu et al teach that the enhanced binding allows the DNA to survive high-stringency washes. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Zierdt et al.

US 2002/0022228 and Calsou et al teach all of the limitations as described above. US 2002/0022228 also teaches washing the array with PBS (phosphate buffer saline solution). However, they do not teach a buffer containing a saline solution and a nonionic surfactant.

Zierdt et al (Appl Environ Microbiol. 38(6):1166-72, 1979, specifically p. 1166) teach using a buffer containing phosphate and Tween 20.

The ordinary skilled artisan, desiring to use a buffer containing a saline solution and a nonionic surfactant would have been motivated to combine the teachings of US 2002/0022228 teaching a method for analyzing DNA repair by excision and resynthesis and Calsou et al teaching measuring nucleotide excision repair and DNA resynthesis, using supercoiled plasmids. with the teachings of Zierdt et al, teaching a buffer containing phosphate and Tween 20, because Zierdt et al state that Tween 20 can partially block strong adherence to a filter. It would have been obvious to one of ordinary skill in the art to use a buffer containing phosphate and Tween 20 because Zierdt et al teach that it is undesirable to have molecules larger than the pore size adhering to the filter, therefore, it is beneficial to use a substance to remove some of those molecules. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent

evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Gelfand et al.

US 2002/0022228 and Calsou et al teach all of the limitations as described above. However, they do not teach exciting the labeled triphosphate and measuring the signal emitted.

Gelfand et al (PNAS 96: 6113-6118, 1999, specifically p. 6113-15) teach using FRET to compare a reference (control) DNA molecule to a DNA molecule which contains a lesion. The molecules are excited, and free energy is measured.

The ordinary skilled artisan, desiring to excite the labeled triphosphate and measuring the signal emitted would have been motivated to combine the teachings of US 2002/0022228 teaching a method for analyzing DNA repair by excision and resynthesis and Calsou et al teaching measuring nucleotide excision repair and DNA resynthesis, using supercoiled plasmids, with the teachings of Gelfand et al, teaching using FRET to compare a reference (control) DNA molecule to a DNA molecule which contains a lesion, because Gelfand et al state that because of the sensitivity of fluorescence, the method requires orders of magnitude less material than other solution methods. It would have been obvious to one of ordinary skill in the art to use FRET because Gelfand et al teach that FRET has high throughput ability. Given the teachings

of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of MPEP 2144.05.

US 2002/0022228 and Calsou et al teach all of the limitations as described above. US 2002/0022228 also teaches incubating for 1 hour and 2 hours at 37°C. However, they do not teach incubating for 3 hours, or teach incubating at 30°C.

MPEP 2144.05 teaches that optimizing concentrations is obvious.

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler,* 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

MPEP 2144.05

Therefore, since there is no evidence that incubating for 3 hours instead of two hours is critical, or that temperature of 30°C instead of 37°C is critical, it would be obvious to use 30°C or to incubate for 3 hours. Also, claim 45 reads "at a temperature of about 30°C", therefore absent evidence to the contrary, 37°C is about 30°C. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Yershov et al.

US 2002/0022228 and Calsou et al teach all of the limitations as described above. However, they do not teach depositing the plasmids on an array with a robot.

Yershov et al (PNAS 93(10):4913-8, specifically p. 4913, 4917) teach depositing the DNA on an array with a robot.

The ordinary skilled artisan, desiring to deposit DNA on an array with a robot would have been motivated to combine the teachings of US 2002/0022228 teaching a method for analyzing DNA repair by excision and resynthesis and Calsou et al teaching measuring nucleotide excision repair and DNA resynthesis, using supercoiled plasmids, with the teachings of Yershov et al, teaching depositing the DNA on an array with a robot, because Yershov et al state that using a robot is efficient for DNA sequence comparisons. It would have been obvious to one of ordinary skill in the art to use a robot because Yershov et al teach that it the robot capacity can be scaled up to allow for high concentrations of DNA to be deposited. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0022228 and Calsou et al as applied to claims 22-25, 29, 31, 33, 38, 41-44, 47 and 50 above, and further in view of Randerath et al.

US 2002/0022228 and Calsou et al teach all of the limitations as described above. However, they do not teach that the labeled triphosphate is labeled with ^{32}P.

Randerath et al (PNAS 78(10):6126-9, 1981, specifically p. 4913, 4917) teach labeling DNA with ^{32}P to test for DNA damage.

The ordinary skilled artisan, desiring to label with ^{32}P would have been motivated to combine the teachings of US 2002/0022228 teaching a method for analyzing DNA repair by excision and resynthesis and Calsou et al teaching measuring nucleotide excision repair and DNA resynthesis, using supercoiled plasmids, with the teachings of Randerath et al, teaching labeling DNA with ^{32}P, because Randerath et al state that labeling DNA with ^{32}P provides an ultrasensitive and rapid assay. It would have been obvious to one of ordinary skill in the art to use ^{32}P because Randerath et al teach that it provides a means for detecting covalent binding of chemicals to DNA, and thus should be suitable for screening potential carcinogens. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/
Examiner, Art Unit 1636

Michele K. Joike
Examiner
Art Unit 1636